

# **EXHIBIT B-11**

**From:** Jacobs, Ed M [ETHUS] <EJacobs3@its.jnj.com>  
**Sent:** Thu, 16 Oct 2014 14:37:11 GMT  
**To:** Smith, Dan [ETHUS] <DJSmith@its.jnj.com>; Hackman, Lee [ETHUS] <LHackma1@its.jnj.com>; Weisberg, Martin [ETHUS] <MWeisbel@its.jnj.com>; Elbert, Katrin [ETHUS] <KElbert@its.jnj.com>  
**CC:** Lamouille, Anthony [JNJCH Non J&J] <alamouil@ITS.JNJ.com>; Meltzer, Jeff [ETHUS Non-J&J] <jmeltzer@ITS.JNJ.com>  
**Subject:** RE: TTV Defect to Harm Map

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Thank you for the feedback and comments this week.  
Attached is the final version I will submit for approval.

I will submit with the required approvers being LCM QE (Lee Hackman) and Medical Director (Martin Weisberg).

Ed j

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From: Jacobs, Ed M [ETHUS]  
Sent: Monday, October 13, 2014 6:21 PM  
To: Smith, Dan [ETHUS]; Zaddem, Vincenza [ETHUS]; Weisberg, Martin [ETHUS]; Meltzer, Jeff [ETHUS Non-J&J]; Hackman, Lee [ETHUS]  
Cc: Lamouille, Anthony [JNJCH Non J&J]  
Subject: RE: TTV Defect to Harm Map

Sorry for my delay in getting these edits completed. Thank you Anthony for your help and additional corrections identified.

Please look at the attached spreadsheet. The Yellow cells are ones with updates. Purple to be deleted.

<< File: 100208442 vDFT2 Incontinence (TTV) Defect to Harms Map.xlsx >>

Let me know if any additional changes are recommended. I plan to initiate the CO for review tomorrow with approvers defined as:

Hackman, Smith and Weisberg

Ed j

-----Original Appointment-----

From: Jacobs, Ed M [ETHUS]  
Sent: Friday, September 12, 2014 2:44 PM  
To: Jacobs, Ed M [ETHUS]; Smith, Dan [ETHUS]; Zaddem, Vincenza [ETHUS]; Weisberg, Martin [ETHUS]; Meltzer, Jeff [ETHUS Non-J&J]; Hackman, Lee [ETHUS]  
Cc: Lamouille, Anthony [JNJCH Non J&J]  
Subject: TTV Defect to Harm Map  
When: Monday, September 29, 2014 10:00 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).  
Where: CR-US-NJ-Somerville-Bldg40-A208A (8)

Conf Call In code: 40691202 Phone: 1-877-5665-9999

Will use communicator to share desktop

This meeting is to review the TVT Defect to Harm Map in preparation for submission for approval.

Ed j

**Placeholder**

**Document produced in native format**

**Revision History for <ADAPTIV Doc # >**

<b>Revision #</b>	<b>Description of Change</b>
1	Original Issue

**Revision History for Form 100148010 Template for Defect to Harms Map**

Revision #	Summary of Change
1	Original Issue

**Note: This Form supports Work Instructions: 100147810 Defect Harms Map Index**

Note: This document is intended for use with Work Instruction 100112176 in the execution of Process Risk Assessment. The listed effect for a defect is

\* The text in the Defect, Defect Description and Product Category columns are taken from specification referenced in column A. Any discrepancies in text are unintentional.  
Note that the Severity Category of S4 represents the "Regulatory Compliance" Risk category as noted/defined in procedure PR-0000564. Items in category are designated

#### 100208442 Incontinence (TVT) Products Defect to Harm Map

Specification #(s) in which Defect is defined	Defect <name and tracking associated number>	Defect Description <if available, copy directly from defect description document>	Product Category	Effect on Use of Released Product	Standardized Hazard < PR-0000564 Ap 2>	Global Harm < PR-0000564 Ap 1>	Severity Category
WI-EMQD10	Foreign substances on packaging and labels Code - A001	Foreign substances on packaging and labels	All	Foreign matter is able to make its way into the surgical site and becomes implanted	GN-01 Residual Foreign Body	Inflammatory or other Unintended Tissue Reaction	S3
WI-EMQD10	Mixture, incorrect or missing batch number or product code Code - A002	Mixture, incorrect or missing batch number or product code	All	Critical label information missing. Batch # or expiry date not readable	GN-03 Loss of traceability	Regulatory Compliance	S4
WI-EMQD10	Internal or external printing Code - A003	Incorrect printed information Unreadable expiry or date superior to the product's expiry date Wrong product code printed on the label	All	Critical label information missing. Batch # or expiry date not readable	GN-03 Loss of traceability	Regulatory Compliance	S4
WI-EMQD10	Incorrect component Code - A004	Wrong raw material/Component used: lid ; box	All	Incorrect component, missing component or lot # of component used results in an inaccurate batch record	GN-03 Loss of traceability	Regulatory Compliance	S4
WI-EMQD10	Missing component Code - A005	Wrong quantity in the packaging (box, blister, etc.)	All	Incorrect component, missing component or lot # of component used results in an inaccurate batch record	GN-03 Loss of traceability	Regulatory Compliance	S4
WI-EMQD10	Damaged, crushed or torn Carton box Code - A006	A box is damaged, crushed, or exhibits one or more tears in the paper.	All	Damage to box results in breach of sterile barrier of the product	BC-01 Biocontamination	Infection	S3
WI-EMQD10	Unsealed Carton box Code - A007	Box without glue or detached with an impact on the product Illegible information	All	Critical label information missing. Batch # or expiry date not readable	GN-03 Loss of traceability	Regulatory Compliance	S4
WI-EMQD10	Labels / Data Matrix Wrong information Code - A008	Data Matrix encoded with incorrect information	All	Critical label information is incorrect.	GN-03 Loss of traceability	Regulatory Compliance	S4
WI-EMQD10	Wrong or missing insert (IFU) Code - A009	Wrong insert (Instructions for Use) used Insert (IFU) missing	All	Critical Information missing	HI-1 Incomplete, inadequate or overly complicated Instructions for Use	Regulatory Compliance	S4
WI-EMQD10	Foreign substance in primary packaging Code - A010	Particle going entirely through the sealing forming a channel	All	Foreign matter is able to make its way into the surgical site and becomes implanted	GN-01 Residual Foreign Body	Inflammatory or other Unintended Tissue Reaction	S3
WI-EMQD10	Assembly or handling error Code - A011	Assembly Error	All	Incorrect component, missing component or lot # of component used results in an inaccurate batch record	GN-03 Loss of traceability	Regulatory Compliance	S4
WI-EMQD10	Components incorrectly placed in the packaging Code - A012	Products not placed properly in spacers/trays inside the sterile barrier	All	Breach in sterile barrier	BC-01 Biocontamination	Infection	S3
WI-EMQD10	Implant/Feuille  Implant/Sheet Code - A013	Caractéristique différente: feuille raide  Different feature : rigid sheet	All	Material properties different from user expectation. Outcomes not as expected	PP-02 Damage, Degradation or Deterioration in function	Failure of Treatment	S3
WI-EMQD10	Seal Integrity Code - A014	Channel going through both sides of the sealing Open Seal	All	Compromised package whose seal may fail during transit to use site. Breach in sterile barrier	BC-01 Biocontamination	Infection	S3
WI-EMQD10	Primary packaging integrity Code - A015	Hole in the primary sterile packaging	All	Compromised package whose seal may fail during transit to use site. Breach in sterile barrier	BC-01 Biocontamination	Infection	S3
WI-EMQD10	Blister / plastic Insert/spacer, deformed or defect in material Code - A016	Blister (thermoform) and/or plastic Insert/spacer/workstation is deformed (cracks or stains) Material defect (Bubbles, embedded particles bigger than 3mm <sup>3</sup> or longer than 6mm)	All	Cracks in blister represent Breach in Sterile barrier	BC-01 Biocontamination	Infection	S3
WI-EMQD10	Lid Seal - TYVEK Transparency (glazing) Code - A017	Lid Seal - TYVEK Transparency (glazing)	All	Compromised package whose seal may fail during transit to use site. Breach in sterile barrier	BC-01 Biocontamination	Infection	S3
WI-EMQD10	Component Mix Code - TVT05	Kit does not contain the correct implant (White / Blue) Assembly error	All	Incorrect component, missing component or lot # of component used results in an inaccurate batch record	GN-03 Loss of traceability	Regulatory Compliance	S4
WI-EMQD10	Plastic Sheath forming defect TVT06	Défaut de formation du plastique  Plastic Sheath forming defect Code - TVT06	All	Needle Sheath slides . Difficulty insertion. Potential for inadvertent implant of sheath material	BC-05 Biocompatibility	Inflammatory or other Unintended Tissue Reaction	S3
WI-EMQD10	Plastic sheath defect Code - TVT10, TVTO-12, TVTRL-01	Plastic Sheath : Hole or tear, burned / curled, Length, width out of tolerance	All	May cause user to have a poor impress of Ethicon quality	No Hazard Identified	No Harm Identified	S1
WI-EMQD10	Plastic sheath defect with protrusion Code - TVT11, TVTO-13, TVTRL-02, TVTOML-13	Plastic Sheath : Crack with mesh protrusion	All	User may not perceive smooth insertion when placing mesh	PP-02 Damage, Degradation or Deterioration in function	Soft Tissue Damage	S2
WI-EMQD10	Prolene mesh Code - TVT12, TVTO-14, TVTRL-03	* Mesh Width or length out of tolerance. * Less than 3 full continuous wales over the length of the mesh. * Edge cut quality * Elongation QOS	All	Material properties different from user expectation. Potential for insufficient material to provide applied pressure to urethra.	PP-02 Damage, Degradation or Deterioration in function	Failure of Treatment	S3
WI-EMQD10	Stains on TVT metallic needle Code - TVT13	Stains on needle	All	May cause user to have a poor impress of Ethicon quality	No Hazard Identified	No Harm Identified	S1
WI-EMQD10	Scratches on metallic needle Code - TVT14, TVT18	Scratches on metallic needle	All	May cause user to have a poor impress of Ethicon quality	No Hazard Identified	No Harm Identified	S1
WI-EMQD10	Burr metallic needle Code - TVT15	Burr in contact with the patient	All	User may not perceive smooth insertion when placing mesh	PP-02 Damage, Degradation or Deterioration in function	Soft Tissue Damage	S2
WI-EMQD10	Tip too sharp or too flat Code - TVT16	Tip too sharp or too flat	All	Sharp tip may injure bowel during passage.	PP-03 Unexpected, ineffective, or Hazardous Interaction With Tissue	Organ Damage	S5
WI-EMQD10	Recovery Needle/sheath thermo Code - TVT19	Heat shrink sheath covers the needle's shoulder	TVT TVTA	User may not perceive smooth insertion when placing mesh	PP-02 Damage, Degradation or Deterioration in function	Soft Tissue Damage	S2
WI-EMQD10	Detachment needles/plastic needle/mesh Code TVT20	Detachment of needle/mesh or needle/plastic	All	Heat shrink tubing is left in patient. Inadvertent implant	PP-02 Damage, Degradation or Deterioration in function	Inflammatory or other Unintended Tissue Reaction	S3
WI-EMQD10	Positionning mesh/needle Code TVT21	Mesh not centered on the second groove of the needle	TVT TVTA	Mesh separates from needle prior to exiting body. New device must be used to complete procedure	PP-02 Damage, Degradation or Deterioration in function	Failure of Treatment	S1
WI-EMQD10	Guide Helical Passer (Handle) Code TVT-06	Cracks	TVTO	May snag glove and cause user to need to reglove. User irritation	No Hazard Identified	No Harm Identified	S1

WI-EMQD10	Assembly Needle/Guide Code TVT-07	Bad attachment of the needle to the handle	TVTO	Needle separates from handle during placement of product in patient	PP-02 Damage, Degradation or Deterioration in function	Organ Damage	S5
WI-EMQD10	TVTO Plastic needle Code TVTO-15	Trou d'introduction du guide endommagé Dimensions out of specification. Tip damaged. <u>Damaged guide introduction hole</u>	TVTO	Guide does not fully extend into needle tip and tip bends or breaks during placement. Inadvertent implant	GN-01 Residual Foreign Body	Inflammatory or other Unintended Tissue Reaction	S3
WI-EMQD10	Mesh/needle assembly Code TVTOML-16	Needles/Sheath/Implant Assembly not correctly welded Detent force out of specification Tip not present	TVTO	Guide does not fully extend into needle tip and tip bends or breaks during placement. Inadvertent implant	GN-01 Residual Foreign Body	Inflammatory or other Unintended Tissue Reaction	S3
WI-EMQD10	Defect on Winged guide (e.g. P18020, P24020) Code TVTO-18, TVTOML-06	Presence of Rust	All	Foreign matter is able to make its way into the surgical site and becomes implanted	GN-01 Residual Foreign Body	Inflammatory or other Unintended Tissue Reaction	S3
WI-EMQD10	Defect on TVTOML mesh (P24001) Code TVTOML-03	<u>Less than three full wales over the length of the mesh</u>	TVT Abbrevio	Insufficient material to provide applied pressure to urethra	PP-02 Damage, Degradation or Deterioration in function	<u>Failure of Treatment</u>	S3
WI-EMQD10	Defect on Prolene® line (7234X8) Code TVTOML-04	Cut / Nick / Shave (diameter reduction or slice separated from material) / Dent (area of 1.5 time bigger than diameter)	TVT Abbrevio	The adjusting strands breaks prior to final tensioning of implant requiring removal/replacement	PP-02 Damage, Degradation or Deterioration in function	Failure of Treatment	S3
WI-EMQD10	Defect on Plastic sheath Code TVTOML-05	Plastic Sheath : Hole or tear.	TVT Abbrevio	Mesh able to prematurely engage with tissue during placement. Difficult to adjust	PP-02 Damage, Degradation or Deterioration in function	Failure of Treatment	S2
WI-EMQD10	Défaut sur le Bouton (P24021) Defect on Button (P24021) Code TVTOML-07	Material /Colorant out of specification	TVT Abbrevio	Poor impression of product quality	No Hazard Identified	No Harm Identified	S1
WI-EMQD10	Plastic Needle (P18005) Code TVTOML-08	Detent force out of specification	TVT Abbrevio	Guide does not fully extend into needle tip and tip bends or breaks during placement. Inadvertent implant	GN-01 Residual Foreign Body	Inflammatory or other Unintended Tissue Reaction	S3
WI-EMQD10	Défaut sur la Boucle (7234X8) Defect on Loop line (7234X8) Code TVTOML-09	Longueur de loop inférieure à 87 mm Loop length less than 87 mm	TVT Abbrevio	User unable to detach placement needle(s) prior to final adjustment. Punctures patient	PP-03 Unexpected, Ineffective, or Hazardous Interaction With Tissue	Soft Tissue Damage	S2
WI-EMQD10	Defect on Plastic needle Assembly (P24244) Code TVTOML-10	Tensile strength of attachment between needle and other components is lower than 2 kgf minimum Sheath/implant not correctly welded <u>Tip not present</u>	TVT Abbrevio	Guide does not fully extend into needle tip and tip bends or breaks during placement. Inadvertent implant	GN-01 Residual Foreign Body	Inflammatory or other Unintended Tissue Reaction	S3
WI-EMQD10	Final Needle Assembly (P24115) Code TVTOML-11	* The placement aid button and needle hole opening is not on the same side of the mesh. * Placement aid loop is not weaved using three full pores on the same column and with one pore skipped in the middle	TVT Abbrevio	The mesh does not remain centered during placement.	PP-03	Failure of Treatment	S3
WI-EMQD10	Defect on Mesh / Positioning line / sheath subassembly (P24100) Code TVTOML-12	knitting Defects, placement of positioning line incorrect in sheath sub-assembly	TVT Abbrevio	Material properties different from user expectation. Potential for insufficient material to provide applied pressure to urethra.	PP-02 Damage, Degradation or Deterioration in function	Failure of Treatment	S3
WI-EMQD10	Defect on plastic Insert/ spacer Code TVTOML-14	Trough depth on plastic Insert/ spacer/ workstation too shallow	TVT Abbrevio	Customer perceives breach in barrier. Poor impression of quality	No Hazard Identified	No Harm Identified	S1
WI-EMQD10	Incorrect Component positioning in plastic Insert/ spacer Code TVTOML-17	Loop-button incorrectly oriented in plastic Insert/ spacer/ workstation	TVT Abbrevio	Poor impression of product quality	No Hazard Identified	No Harm Identified	S1
WI-EMQD10	Guide (Helical Passer) Code TVTOML-19	Cracks	TVT Abbrevio	Foreign matter is able to make its way into the surgical site and becomes implanted	GN-01 Residual Foreign Body	Inflammatory or other Unintended Tissue Reaction	S3
WI-EMQD10	Trocars sheath defect Code TVTRL-04	Cut-out not present Trocars sheath tip damaged. <u>Damaged guide introduction hole</u> Tip radius or internal diameter of tip or outer diameter or punch side hole location out of specification	TVT Exact	Mesh able to prematurely engage with tissue during placement. Difficult to adjust	PP-02 Damage, Degradation or Deterioration in function	Failure of Treatment	S2
WI-EMQD10	Trocars Sheath/Implant Assembly defect Code TVTRL-05	Trocars Sheath/Implant Assembly not correctly welded. Trocars sheath tip not present.	TVT Exact	Foreign matter is able to make its way into the surgical site and becomes implanted	GN-01 Residual Foreign Body	Inflammatory or other Unintended Tissue Reaction	S3
WI-EMQD10	Injection molded process defects for the Trocar. Code TVTRL-07	*Cracks *Trocars sheath lock not present	TVT Exact	Foreign matter is able to make its way into the surgical site and becomes implanted	GN-01 Residual Foreign Body	Inflammatory or other Unintended Tissue Reaction	S3
WI-EMQD10	Logo Appearance/ Discoloration. Code TVTRL-08	Gynecare logo illegible on the handle Trocar handle Discoloration <u>Trocar shaft surface roughness out of specification</u>	All	Poor impression of product quality	No Hazard Identified	No Harm Identified	S1
WI-EMQD10	Missing component Code TVTRL-10	Retainer lid is missing.	TVT Exact	Incorrect component, missing component or lot # of component used results in an inaccurate batch record	GN-03 Loss of traceability	Regulatory Compliance	S4
WI-EMSP026	Finished product Storage Temperature Exceeded	Products stored prior to release at mean temperatures in excess of product labeling	All	Material properties different from user expectation. Outcomes not as expected	PP-02 Damage, Degradation or Deterioration in function	Failure of Treatment	S3